K062441

Page 183

510(k) SUMMARY

BÂRRX Medical's HALO^{90} Coagulation System

1. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

NOV 14 2006

Phone: (408) 328-7302
Facsimile: (408) 328-7395

Contact Person: Viorica Filimon

Date Prepared: August 19, 2006

2. Name of device and Name/Address of Sponsor:

HALO^{90} Coagulation System
HALO^{90} Coagulation Catheter
HALO^{90} Energy Generator

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

3. Common or Usual Name(s):

Electrosurgical Coagulation System

4. Classification Name:

Product code: GEI
CFR Section: 878.4400 Electrosurgical, cutting & coagulation & accessories
Device Class: II
Classification panel: General & Plastic Surgery

5. Predicate Devices

- HALO^{90} Energy Generator model 1100C-115C (K060169) manufactured by Stellartech Research;
- HALO^{360} Energy Generator model 1100C-115B (K051168) manufactured by Stellartech Research;
- Stellartech Coagulation System 2, model 1100C-115A (K050831) manufactured by Stellartech Research;

6. Intended Use / Indications for Use

The HALO^{90} Coagulation System intended use is for the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract.

The HALO^{90} Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

7. Technological Characteristics

The HALO^{90} Coagulation System consists of the HALO^{90} Energy Generator model 90-9000 with a disposable single-use HALO^{90} Coagulation Catheter, output cable, and a footswitch. The HALO^{90} Coagulation System performance and mode of operation is substantially equivalent to the already cleared HALO^{90} Coagulation System, HALO^{360} Coagulation System, and Stellartech Coagulation System 2.

HALO^{90} Coagulation Catheter

There are no changes associated with the HALO^{90} Coagulation Catheter model 1520F.

HALO^{90} Energy Generator

The HALO^{90} Energy Generator model 90-9000 is configured with an output cable (model 90-9010), a footswitch (model 90-9020) and a power cord.

The HALO^{90} Coagulation Generator supplies up to 150 watts of radiofrequency power at 460 kHz in a bipolar mode under power control while continuously monitoring and displaying power density, and energy density. Energy

density and power are displayed to allow homogeneous energy delivery equivalent to the HALO^{90} Energy Generator model 1100C-115C.

8. Substantial Equivalence

The HALO^{90} Coagulation System (generator model 90-9000) and the predicate devices: HALO^{90} Coagulation System (generator model 1100C-115C), HALO^{360} Coagulation System and Stellartech Coagulation System 2 have the same or similar intended use, indications for use, technological characteristics, and principles of operation. The technological differences between the HALO^{90} Coagulation System and its predicates are:
(1) Simplification of the generator and elimination of the unused pneumatic systems for inflation/deflation capability;
(2) Changes in the hardware implemented to establish an optimum RF power output for the impedance range defined for the clinical application;
(3) Minor modification of the generator software to support the changes in the hardware design.
(4) Change of the design and manufacturing facility to the Aubrey Group;

All these differences were evaluated on bench and did not raise questions regarding safety and efficacy. Thus the devices are equivalent.

V. 510(K) SUMMARY

The Company's 510(k) Summary is provided in pages **19-21** below.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BÂRRX Medical, Inc.
% Hogan & Hartson, L.L.P.
Mr. Jonathan S. Kahan
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

NOV 14 2006

Re: K062441
Trade/Device Name: HALO^{90} Coagulation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 17, 2006
Received: October 17, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062441

1. Indications for Use Statement

510(k) Number (if known):_____

Device Name:

Indications for Use:

The HALO^{90} Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Prescription Use __✓___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062441 Page ___ of ___